

### REMARKS

In the Final Official Action dated July 15, 2002, claims 39, 40, 42 and 43 are pending. Claims 39-40 and 42-43 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enabling support. Claims 39 and 42 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly including new matter.

Applicants, through the undersigned, wish to thank Examiner Ewoldt for the courtesy and assistance provided in connection with a telephonic interview conducted on December 17, 2002.

This response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance or at least in better position for appeal. Favorable consideration of all pending claims is therefore respectfully requested.

Claims 39, 40, 42 and 43 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling support. The Examiner specifically alleges that Applicant "has not established a link between the *in vitro* T-cell proliferation assays of the specification and the method of treating and diagnosing for IDDM." The Examiner further alleges that immunopeptide therapy must be considered highly unpredictable and must be considered on a peptide-by-peptide basis.

During the course of interview, the Examiner indicated that Applicants should provide some evidence that the peptides of the present invention (the subject of claims 39 and 40) are not only useful as therapeutic agents but also can be considered useful for other purposes. Applicants submit that as diagnostic agents the claimed peptides can react with T-cells from individuals with clinical or preclinical IDDM, can induce T-cell proliferative

responses, can be used for measuring reactivity of a subject's cells to the IDDM autoantigen, and can be used in a diagnostic kit for assaying T cells. Support for claims 39-40 can be found throughout the specification, for example at page 2, lines 21-32, page 3, lines 7-10 and lines 17-22, page 7, lines 4-19, page 9, line 10 to page 11, line 1, Examples 4, 5 and 6. In an effort to expedite favorable prosecution, Applicants have cancelled claims 42-43, without prejudice. Applicants reserve the right to file one or more divisional applications directed to the subject matter of the cancelled claims.

Accordingly, the rejection of claims 39, 40, 42 and 43 under 35 U.S.C. §112, first paragraph is overcome and withdrawal thereof is respectfully requested.

Claims 39 and 42 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly including new matter. Specifically, the Examiner alleges that the specification and the claims as originally filed do not provide support for X<sub>2</sub> having an amino acid sequence from 10-13 residues. The Examiner indicates that the specification discloses an X<sub>2</sub> substituent of 10-50, 10-30, or 10-15 amino acids.

In response, Applicants respectfully submit that X<sub>2</sub> is a stretch of amino acid residues derived from or contiguous within amino acids 506 to 518 inclusive of human GAD 65 or amino acids 24 to 36 inclusive of human proinsulin. Notably, the peptides of SEQ. ID Nos. 1 and 2 are each 13 amino acids in length, thus explicitly supporting the recitation of "X<sub>2</sub> is an amino acid sequence of 10 to 13 amino acids" (see claim 39). The amendment to claim 13, thus added no new matter as stated in the amendment filed April 25, 2002, pp. 5-6.

Accordingly, the rejection of claims 39 and 42 under 35 U.S.C. §112, first paragraph is overcome and withdrawal thereof is respectfully requested.

Accordingly, in view of the foregoing remarks, the present application is deemed to be in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Peter I. Bernstein', with a stylized flourish at the end.

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